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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,383	08/21/2003	Vincent G. Copa	AMS0008/US	9726

33072 7590 08/20/2008
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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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08/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/646,383	Applicant(s) COPA ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 04/15/2008.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 7-9, 12-14, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Salama** (U.S. Patent No. **5,306,226**) in view of Orban, III, hereinafter "**Orban**" (U.S. Pub. No. **2005/0251155**).

Claims 1-3, 7-9, 12-14, and 26-31: Salama discloses a hollow elongate, flexible catheter body having a proximal end and a distal end, an inflatable balloon **26** at the distal end in the bladder, a drainage aperture **18** at the distal end and a drainage means **15** connected to the drainage aperture for draining urine from a bladder, and tissue approximating structure or means **36** on the catheter body capable of contacting bladder, tissue of a perineal wall, urethral tissue, and combinations of these for holding severed tissue in contact for healing, wherein the inflatable balloon is on a proximal side of the drainage aperture and the tissue approximating structure or means is on a proximal side of the inflatable balloon (Figure 2, col. 2, lines 18-56).

Salama discloses the claimed device, including a tissue approximating structure or means located on a proximal side of the drainage aperture, *except for* the tissue approximating structure or means being at the distal end of the catheter body (wherein "distal end" is considered as a "function of an anastomosis device that is inserted into a body during an anastomosis procedure and that then becomes located in the region of the bladder, urethra, urethral stump, and perineal wall," as disclosed in the specification, page 3, lines 29-31 to page 4, line 1), and the tissue approximating structure or means comprising a tine, probe, prod, or needle, or multiple opposing tines.

Orban teaches a tissue approximating structure or means **110, 126** at the distal end of a catheter body **180** having a catheter body wall at its distal end, and it is in located in the region of the bladder "**B**," urethra "**U**," urethral stump "**S**," wherein the tissue approximating structure or means comprises a tine, prod, or needle, or multiple opposing tines and can be extended and retracted from the catheter body wall to contact tissue selected from the group consisting of bladder tissue, urethral tissue, urethral stump tissue, and perineal wall tissue (Figures 7-10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue approximating structure or means comprising multiple opposing tines at the distal end of a catheter body, as taught by Orban, to Salama in order to facilitate the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines, making the process more efficient and simple to use (page 1, paragraphs 9 and 13).

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3. Claims 4-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Salama** (U.S. Patent No. **5,306,226**) and **Orban** (U.S. Pub. No. **2005/0251155**), as applied to Claims 1, 3, and 9 above, and further in view of **Biggs et al.** (U.S. Patent No. **6,599,311**).

Claims 4-6 and 11: Salama and Orban disclose the claimed device, including an inflation lumen **20** extending from the proximal end to the balloon, a drainage lumen connected to the distal end extending from a drainage aperture **18** at the distal end to a drainage port **15** at the proximal end (Salama, Figure 2), and both distal and proximal, movable elongate tines (Orban, Figure 9B), *except for* the tines being positioned to extend through apertures in the hollow catheter body and an actuating mechanism that is connected to the tissue approximating means that can be extended and retracted from apertures in the catheter body, and the actuating mechanism extends through a lumen along a portion of the length of the device to the proximal end which actuates the tissue approximating means.

Biggs et al. teaches tines **266** being positioned to extend through apertures **264** in a hollow body catheter **260** (Fig 31B and col. 20, lines 1-7). Biggs et al. also teaches an actuating mechanism **202** that is connected to a tissue approximating means **204** that can be extended and retracted from apertures in the catheter body, and the actuating mechanism may extend through a lumen along a portion of the length of the device to the proximal end which actuates the tissue approximating means (Figures 24A-24B, col. 19 lines 1-10). Biggs et al. teaches that this mechanism allows for the anchoring device

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to be advanced into a passageway in a non-extended form until it reaches a position where it can be attached to tissue and may subsequently be extended through the apertures (col. 2, lines 62-67 and col. 3, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide extendable tines through apertures in a hollow catheter and an actuating mechanism that is connected to and actuates the tissue approximating means, as taught by Biggs et al., to Salama and Orban in order to move the catheter, or the device within the catheter, without being engaged to the tissue until it is at a desired location at which point the tines can be extended.

Response to Arguments

3. Applicant's arguments filed 04/15/2008 have been fully considered but they are not persuasive.
4. The applicant argues that the tissue approximating structure in the Orban reference is not capable of being extended and retracted from a catheter body wall. However, as seen in Figures 7-10, the tissue approximating structure 110, 126 may be extended and retracted from a catheter body wall of 180, and therefore reads on this limitation.
5. Applicant also argues that Orban is not combinable with Salama since it would require one to ignore the specific and exclusive manner in which the Orban reference operates. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed

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invention must be expressly suggested in any one or all of the references.

Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. As maintained above, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue approximating structure or means comprising multiple opposing tines at the distal end of a catheter body, as taught by Orban, to Salama in order to facilitate the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines, making the process more efficient and simple to use (page 1, paragraphs 9 and 13).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731